DETAILED ACTION

1. The following is in response to the amendment filed December 29, 2009.

2. Claims 1-72 are currently pending, with claims 12-69 withdrawn from consideration

Claim Rejections - 35 USC § 112

3. The amendment to claim 1 is acknowledged. According the rejections of claims 1-11 and 70-72 under 35 U.S.C. 112, first paragraph and second paragraph, have been withdrawn.

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Lebouitz et al. (US 6,972,199, hereinafter "Lebouitz"). Lebouitz discloses an end effector (Fig 3) configured and adapted to engage tissue; and a plurality of micro-electromechanical system (MEMS) devices (individual sensors forming sensor array 45 and sensor 40) disposed along a length of the surgical instrument for sensing a condition (col 5, ll 29-38). Lebouitz discloses, the sensor array (45) comprises a "plurality of individual sensors", in which the sensors are clearly spaced apart along a length at the distal end of the surgical instrument (Fig 3; col 5, ll 31-33). Each MEMS device is a single integral device that is operationally independent of other MEMS devices configured to communicate with the surgical instrument. The MEMS devices include two or three orthogonal assemblies of MEMS devices integrated together to form a two or three dimensional acceleration measuring device for determining the position of the surgical instrument relative to target tissue (col 2, ln 56 –col 3, ln 13 and col 3, ll 31-41). At least one control operation of the surgical instrument is automatically adjusted based on feedback

received from the at least one MEMS device via at least one comparator for comparing at least one of a second condition and a measured parameter against at least one of a predetermined value (col 7, ll 3-17).

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1-10, 70, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hooven (US 5,518,163) in view of Wang et al. (US 2004/023652, hereinafter "Wang") and Lebouitz (US 6,972,199). Hooven discloses the invention substantially as claimed including a surgical stapler (Fig 2) comprising a handle assembly (40), an elongate member (41), and an end effector (42). The end effector (Fig 6) comprises a staple cartridge assembly (74) and an anvil (75) operatively associated with the staple cartridge. The staple cartridge and anvil each have tissue contacting surfaces for engaging tissue therebetween. The device comprises a plurality of sensors, or MEMS devices (including 163 and 164 in Figure 17), to transmit various types of information during the operation of the instrument including the movement of the various elements used to drive the staples into the tissue, sense whether or not the appropriate tissue is in the appropriate position, and physical parameters of the surrounding environment such as blood oxygen content, tissue density of adjacent tissue or various hemostasis characteristics of adjacent tissue (col 6, ll 25-48; col 7, ll 43-50). The sensors, or MEMS devices, are connected to a microprocessor/controller to automatically adjust the control of at least one operation of the surgical instrument based on feedback from the MEMS device via a comparator for comparing at least one of a second condition and a measured parameter against at least predetermined value (col 8, ll 21-50). Hooven discloses all the sensors, or MEMS

devices, are connected to a microprocessor/controller (203) via an interface cable (205) (col 8, ll 36-37) and that many contacts and sensors may be located in the handle portion of the instrument so that the end effector, or head end, of the instrument may be kept as small as possible (col 6, ll 26-30). Additionally, MEMS devices are located on an inner clamping portion of the end effector (Fig 17).

However, Hooven does not disclose the MEMS devices include two or three orthogonal assemblies of MEMS devices integrated together to form a two or three dimensional acceleration measuring device for determining the position of the surgical instrument relative to target tissue. Lebouitz discloses a surgical instrument comprising a plurality of sensors, or MEMS devices (individual sensors forming sensor array 45). Lebouitz teaches a two or three dimensional acceleration measuring device for determining the position of the surgical instrument relative to target tissue (col 2, ln 56 –col 3, ln 13 and col 3, ll 31-41). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Hooven such that the MEMS devices included two or three orthogonal assemblies of MEMS devices integrated together to form a two or three dimensional acceleration measuring device to provide the user with precise information about the movement of the surgical instrument with respect to the target tissue.

8. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hooven (US 5,518,163) and Lebouitz (US 6,972,199), as applied to claim 9 above, further in view of Racenet et al. (US 2004/0267310, hereinafter "Racenet"). Hooven and Lebouitz disclose the invention substantially as claimed as shown above. However, Hooven discloses the device is a linear stapler capable of performing an endoscopic gastrointestinal anastomosis and does not disclose the device is an annular stapler. Racenet discloses a similar surgical stapler and teach the

stapler may either be linear (Figure 15) or annular (Figure 19) depending on the desired surgical procedure. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Hooven and Lebouitz such that the anvil and cartridge were designed as an annular stapler according to the teachings of Racenet such that the device may more readily perform an end-to-end anastomosis.

9. Claim 71 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hooven (US 5,518,163) and Lebouitz (US 6,972,199), as applied to claim 1 above, further in view of Wang et al. (US 2004/023652, hereinafter "Wang"). Hooven and Lebouitz disclose the invention substantially as claimed as shown above. However, Hooven does not disclose a portion of the plurality of MEMS is positioned on an elongated body of the surgical instrument. Wang discloses a robotic surgical instrument and teaches several sensors, or MEMS devices (172, 178, 182), are disposed at various joints of the device to provide position information during use of the surgical instrument (¶0024; Figures 2-3). Furthermore, Wang teaches the arm (134), or elongated body, includes a plurality of position sensors (172, 178, 182) to feedback the relative position of the handle (¶0089-0090). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Hooven such that each joint and the elongated member additionally comprised position sensors, or MEMS devices, to provide the user with precise information about the movement of the end effector and/or elongate member with respect to the handle and/or the patient.

Response to Arguments

10. Applicant's arguments filed December 29, 2009 have been fully considered but they are not persuasive.

11. Regarding the rejection of claims 1-3 under Lebouitz, Applicant argues Lebouitz does not disclose a plurality of discrete MEMS devices, but rather only teaches a sensor array located on only one portion (i.e. distal portion or blade) of the cutting instrument. The examiner respectfully disagrees. Although the sensors are formed on a single silicon substrate, each sensor element, or MEMS device, is a separate, distinct element (Fig 3; col 5, ll 31-33). The examiner notes Applicant does not claim each MEMS element is fabricated on a separate semiconductor, or silicon, substrate. Furthermore, although the sensors are located only at the distal end of the device, they are still spaced apart along a length of the device. The examiner notes Applicant does not claim the MEMS devices are evenly spaced apart along a length of the device extending from the proximal end to the distal end of the device, nor does applicant claim specific locations for the MEMS devices. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

12. Regarding the rejection of claims 1-10 and 70-72 under Hooven, Wang, and Lebouitz, Applicant argues Hooven fails to disclose MEMS sensors that are integrated devices. The examiner respectfully disagrees. Hooven teaches a plurality of MEMS sensors that are clearly spaced apart along a length of the device. For example, elements 163 and 164 are clearly spaced apart as shown in Figure 17. Furthermore, Hooven teaches additional sensors located in the handle (col 6, ll 25-48; col 7, ll 43-50), which is clearly spaced from elements 163 and 164 located at the distal end of the end effector. Again, the examiner notes Applicant does not claim the MEMS devices are evenly spaced apart along a length of the device extending from the proximal end to the distal end of the device, nor does applicant claim specific locations for the MEMS devices. Although the claims are interpreted in light of the specification, limitations from

the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

13. Applicant additionally argues Wang teaches sensors located only on the robotic arm, which is merely a portion of the entire system and thus does not cure the deficiencies of Hooven. The examiner respectfully disagrees. Wang clearly teaches position sensors (at least 172, 178, 182) disposed on an elongated body of the instrument. The examiner notes Wang is used to teach position members along at least the elongate body to improve the capability of the device to provide information regarding the movement and positioning of the device.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe
April 22, 2010

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Examiner, Art Unit 3734

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